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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant	:	Mitchell et al.			
Serial. No	:	10/075,028	Examiner	:	Vivlemore, Tracy A.
Filed	:	February 12, 2002	Group Art Unit	:	1635
For	:	METHODS AND COMPOSITIONS FOR USE IN SPLICEOSOME MEDIATED RNA *TRANS*-SPLICING			

RESPONSE TO RESTRICTION REQUIREMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450.

October 14, 2004
Date of Deposit

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Commissioner for Patents
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Sir:

This paper is in response to the Office Communication dated June 2, 2004 for the above-identified application. Applicants request a four month extension of time and enclose the required fee as set forth in 37 C.F.R. § 1.17(a)(4).

The Examiner has issued a restriction requirement and requires selection of one of two groups of claims for prosecution in this application. The Examiner has placed the pending claims into the following groups:

Group I: Claims 1-2, 4-18, are drawn to a method of producing chimeric RNA in a cell wherein the nucleic acid molecule contains a 3' splice acceptor site, classified in class 435, subclass 91.1.

Group II: Claims 3, 5-15, drawn to a method of producing chimeric RNA in a cell wherein the nucleic acid molecule contains a 5' splice site, classified in class 435, subclass 91.1.

In support of the present restriction requirement, the Examiner has alleged that the subject matter of the pending claims represent distinct inventions. According to the Examiner, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects. The Examiner alleges that the different invention of the groups have different modes of operation. The Examiner alleges that invention I operates with a nucleic acid which contains a 3' splice region comprising a branch point, a pyrimidine tract and a 3' splice acceptor site, while invention II allegedly operates with a nucleic acid which contains a 5' splice site. Moreover, the Examiner alleges that because the inventions are distinct for the stated reasons, the restriction for examination is indicated as proper. Applicants respectfully traverse.

There are two criteria for a proper requirement for restriction between patentably distinct inventions (see MPEP § 803). First of all, the inventions must be independent (see §§ 802.01, 806.04, 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)). Secondly, there must be a serious burden on the Examiner if restriction is required (see MPEP § 808.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02). MPEP § 803 also states that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner *must* examine it on the merits, even though it contains claims to distinct or independent inventions." (Emphasis supplied).

Applicants respectfully submit that the subject matter of the two Groups is not independent. A test for independence is whether two different combinations are not disclosed as capable of use together, have different modes of operation, different functions or different effects (MPEP §806.04). The methods claimed in both groups employ the use of pre-trans-splicing molecules (PTM) that comprise either a 3' acceptor splice site or a 5' donor splice site. In both cases, a PTM is targeted to a pre-mRNA to create a trans-spliced chimeric RNA product comprising sequences from both the PTM and the target pre-mRNA. When the PTM contain only a 3' acceptor site, the chimeric RNA product of the trans-splicing reaction generated comprises the nucleotide sequence to be trans-spliced in a 3' position relative to the PTM sequences remaining in the product (see Figure 1C, relative position of the DT-A sequences and E1). When the PTM contains only a 5' donor site, the the chimeric RNA product of the trans-splicing reaction comprises the nucleotide sequence to be trans-spliced in a 5' position relative to the PTM sequences remaining in the product. Under both scenarios, the same trans-splicing mechanism is used, thereby employing the same mode of operation. The specification also discloses the use of a PTM containing both a 3' acceptor splice site and a 5' donor splice site (see Figure 5) used in a double trans-splicing reaction to produce a chimeric RNA product, where the nucleotide sequence to be trans-spliced, i.e. mini exon, is transpliced within PTM sequences, being in both 3' and 5' positions relative to PTM sequences. Therefore, the subject matter of Groups I and II recite methods that are capable of use together, have a similar mode of operation and create a similar RNA product.

Applicants also submit that the subject matter of the two Groups are related as subcombinations, but not patentably distinct. The subcombinations of Groups I and II may be used together, e.g. for double trans-splicing reactions. However, as discussed above, the

mechanism employed in the methods recited in claims of Groups I and II are the same and, therefore, the groups are not distinct.

Applicants further submit that the claims are connected by a single, searchable unifying relationship. They are classified into the same class (435) and subclass (91.1), they do not have a separate status forming a separate subject for inventive effort, and a search would not require a different field of research. Therefore, applicants assert that the Examiner would not be seriously burdened by searching and examining all of the claims of these two groups in a single application. For the foregoing reasons, Applicants request withdrawal of the restriction requirement.

Should the Examiner not find the traversal persuasive, in order to be fully responsive, Applicants elect the subject matter of group I, consisting of claims 1-2, 4-18, with traverse and without prejudice to the prosecution of the subject matter of non-elected claims in other patent applications.

Applicants request a four month extension of time and enclose the required fee as set forth in 37 C.F.R. § 1.17(a)(4). Applicants do not believe that any additional fee is required in connection with the submission of this paper. However, should any fee be required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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